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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/385,405	08/30/1999	WILLIAM J. SCHMIDT	671.1.002CIP	9104

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WATOV & KIPNES PC
P O BOX 247
PRINCETON JUNCTION, NJ 08550

EXAMINER
POPOVICS, ROBERT J

ART UNIT	PAPER NUMBER
1723	27

DATE MAILED: 05/21/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

R-27

Office Action Summary

Application No.	Applicant(s)
09/385,405	Schmidt
Examiner	**Group Art Unit**
Popovics	1723

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- [X] Responsive to communication(s) filed on 2/11/02.
- [X] This action is FINAL.
- [ ] Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

- [X] Claim(s) 71-83 is/are pending in the application.
- Of the above claim(s) _____ is/are withdrawn from consideration.
- [ ] Claim(s) _____ is/are allowed.
- [X] Claim(s) 71-83 is/are rejected.
- [ ] Claim(s) _____ is/are objected to.
- [ ] Claim(s) _____ are subject to restriction or election requirement

Application Papers

- [ ] The proposed drawing correction, filed on _____ is [ ] approved [ ] disapproved.
- [ ] The drawing(s) filed on _____ is/are objected to by the Examiner
- [ ] The specification is objected to by the Examiner.
- [ ] The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- [ ] Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119 (a)-(d).
  - [ ] All [ ] Some* [ ] None of the:
    - [ ] Certified copies of the priority documents have been received.
    - [ ] Certified copies of the priority documents have been received in Application No. _____.
    - [ ] Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a))

*Certified copies not received: _____.

Attachment(s)

- [ ] Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- [ ] Interview Summary, PTO-413
- [ ] Notice of Reference(s) Cited, PTO-892
- [ ] Notice of Informal Patent Application, PTO-152
- [ ] Notice of Draftsperson's Patent Drawing Review, PTO-948
- [ ] Other _____

Office Action Summary

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 71-83 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Newly submitted claim 71 now recites ***"said waste material containing at least one first component which can not effectively be separated from the first liquid into a non-solvent based layer."*** This recitation is unsupported by the originally filed specification. Newly submitted claim 72 goes on to claim ***"The method of claim 1 wherein the first component is selected from oily type materials, particulates and combinations thereof having an affinity for the solvent.*** The specification does not say anything about any materials having ***"an affinity for the solvent."*** These recitations constitute new matter.

3. Claim 72 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicant's originally filed specification fails to teach those skilled in the art how to differentiate

between those ***"particulate and/or oily type"*** contaminants of a trace nature from those having an affinity for the solvent based layer, and **now** asserted to be the subject of invention.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 71-83 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With respect to newly submitted claim 71, it is unclear what Applicant intends by the recitation ***"said waste material containing at least one first component which can not effectively be separated from the first liquid into a non-solvent based layer."*** It is unclear what Applicant intends by ***"effectively,"*** in the context used. Is this intended to refer to residual or trace amounts? It is unclear why this ***"first component"*** cannot be effectively separated.

Applicant has argued (Response - Paper no. 26):

> Reference is first made to page 13, lines 11-13 wherein it is stated that the separated solvent based layer (e.g., aqueous layer) contains particulates and/or oily type materials (the contaminants of interest in the present invention). (Response pg. 7, lines 8-10)
>
> As will become more fully apparent from the discussion below, the present invention is principally concerned with removing those contaminants which reside in the **solvent based layer** and not in the non-solvent based layer which is the subject of the reference cited herein (U.S. Patent No. 5,288,408). (Response pg. 7, lines 17-21)

These arguments have raised new issues requiring clarification. With respect to the first sentence, Applicant has positively asserted that ***"the solvent based layer (e.g., aqueous layer) contains particulates and/or oily type materials (the contaminants of interest in the present invention)."*** In other words, Applicant has asserted that at least one of these components is

necessarily present. This is inconsistent with the specific portion of the specification referenced by Applicant. The referenced sentence (i.e., page 13, lines 11-13) begins with the word ***"If."*** Specifically, the sentence appearing at page 13, lines 11-13 reads: **"If the separated aqueous layer contains particulates and/or oily type materials, the aqueous layer may then be treated, to remove residual oils and/or particulates by means of hot filtration processes as more fully described below."** Given that there may not be any of the ***"the contaminants of interest in the present invention"*** **present**, as Applicant's specification makes clear, the meaning of claim 71 and those claims dependent thereon, is unclear, when those contaminants are not present. Moreover, it is unclear how one skilled in the art would differentiate between the two different types (i.e., those having an affinity for the solvent based layer, and those not having said affinity) of contaminants argued to be present in Applicant's most recent response, since Applicant's **originally filed** specification makes no such distinctions. In other words, it is unclear how potential infringers would be put on notice.

6. Claims 71-83 are rejected under 35 U.S.C. 112, second paragraph, as failing to set forth the subject matter which applicant(s) regard as their invention. Evidence that claims 71-83 fail(s) to correspond in scope with that which applicant(s) regard as the invention can be found in Applicant's specification at page 4, lines 1-16, and page 5, lines 3-8. There, Applicant has stated (when discussing the Schmidt et al. Patent - U.S. Patent No. 5,288,408) **"A pure, concentrated aqueous gelatin-glycerin solution results which may be stored or further prepared for immediate reuse. Although this process lends itself to the removal of dyes and active ingredients with additional chemical reactions and processing, such dyes, active**

ingredients, and glycerin are not removed *in situ*", and this statement indicates that the invention is different from what is defined in the claim(s) because the claims fail to mention anything about being ***"in situ."*** One skilled in the art reading the cited portions of the specification would clearly agree that Applicant had admitted that recycling gelatin-based encapsulation waste material using the method disclosed in the '408 patent resulted in ***"A pure, concentrated aqueous gelatin-glycerin solution,"*** but that Applicant's instant invention somehow involved ***"in situ"*** processing.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 71-83 are rejected under 35 U.S.C. 102(b) as being anticipated by Schmidt (US 5,288,408).

9. In the '408 patent to Schmidt, one of the objects is stated to be:

> Still another object of the present invention is to provide a recycled gelatin product with chemical and physical properties identical to virgin gelatin such that reuse may be successfully accomplished.

10. At column 3, the following is disclosed:

> The soft elastic capsule-forming material will thus be used to enclose active ingredients in the form of powders, liquids or combinations thereof. Oils, such as vitamin A, vitamin E and beta-carotene, for example, are frequently encapsulated in the pharmaceutical industry. Additionally, other oils like mineral oil may be used to coat the outer surface of the gel-capsule during processing. Thus, it can be seen that

> the encapsulation waste product may have many components to be removed for reuse. In some instances, **coloring agents and preservatives may also be incorporated into the encapsulation melt**. Commonly used preservatives are methyl- and propylparabens and sorbic acid.
>
> As stated above, present methods of encapsulation lose as much as 50% of the melt during processing, the balance of which is either discarded as a waste by-product or **recycled**. **The latter option requires the removal of all of the above components with the exception of gelatin and glycerine.** The present invention provides a novel and efficient method of accomplishing same without experiencing the shortcomings of the prior art.

11. At column 4, lines 22-31, it is disclosed that:

> Next, **the lower phase is hot filtered to remove any remaining traces of oil or other contaminants**. Stainless steel filtration equipment may be employed such as a plate filter, or a coated plate filter like, for example, a Sparkler filter. Alternatively, nutche filters of the Rosenmund type or **cartridge filters** may be used for the purpose. Here again, the residue may be recaptured for further separation and purification if desired although the amounts involved at this point may not warrant the effort.

12. Claim 6 teaches:

> 6. The process for recovering and purifying waste gelatin and glycerine of claim 1, wherein the step of hot filtering said aqueous gelatin/glycerine solution is accomplished by use of one of the following filters: (a) a plate filter; (b) a coated plate filter; (c) a nutche filter; or **(d) a cartridge filter.**

13. Claim 20 teaches:

> 20. The apparatus of claim 12 wherein said means for hot filtration is a **cartridge filter.**

14. In order to remove ***"all of the above components,"*** including ***"traces"*** of ***"coloring agents," "oils and other contaminants,"*** to attain a ***"recycled gelatin product with chemical and physical properties identical to virgin gelatin,"*** any ***"cartridge filter"*** used would necessarily have the ability, regardless of the filtration process label placed upon it, to accomplish this task. That is to say that any ***"cartridge filter"*** used would have inherently possessed the

ability to accomplish the stated objective. The '408 patent is clear, that a ***"cartridge filter"*** may be used ***"to remove any remaining traces of oil or other contaminants"*** from the aqueous/lower phase! With respect to newly added claim 72, the '408 process will inherently remove all particulate and oily type contaminants.

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

16. Claims 71-83 are alternatively rejected under 35 U.S.C. 103(a) as being unpatentable over Schmidt et al. (U.S. Patent No. 5,288,408).

Schmidt et al. disclose a method of gelatin recovery. As illustrated in Fig. 1, waste material is dissolved with a solvent in an agitated tank and separated into an aqueous/lower phase stream and an upper/organic phase stream. The resultant aqueous phase stream is then subjected to heat and hot filtered, ***"to remove any remaining traces of oil or other contaminants."*** A resultant gelatin/glycerine filtrate is then heated and subjected to vacuum distillation in order to concentrate (i.e., dewater) the resultant, purified filtrate. The recovered gelatin and glycerine may then be immediately re-used (col. 2, lines 33-35 & col. 5, lines 5-10). Beyond disclosing the use of a "cartridge filter" as one possible type of filter to be used, the '408 patent does not go into the details of the pore size, material of construction, etc., of a "cartridge filter" which would be

suitable for the stated purpose. Obviously, no such details were provided, since Schmidt et al. knew that the selection of a such filter would have been well within the purview of the skilled artisan. Indeed, numerous filters existed prior to issuance of the '408 patent which could have handled the separation of "trace" amounts of oil, or "other contaminants" from a liquid stream.

The various temperature/pressure ranges, dilution volume ranges, etc. absent a showing of unexpected results or criticality specifically associated therewith, are considered obvious over the references as applied above. With respect to newly added claim 72, the '408 process will inherently remove all particulate and oily type contaminants.

Response to Arguments

17. Applicant's arguments filed February 11, 2002 have been fully considered but they are not persuasive.

Applicant has argued:

As will become more fully apparent from the discussion below, the present invention is principally concerned with removing those contaminants which reside in the solvent based layer and not in the non-solvent based layer which is the subject of the reference cited herein (U.S. Patent No. 5,288,408). (Response pg. 7, lines 17-21)

Applicant goes on to argue:

The Schmidt et al. '408 process as more fully discussed below, is concerned with removing the remaining trace amounts of the non-solvent based contaminants from the non-solvent based layer but does not teach or suggest any process for removing contaminants

which have an affinity for the solvent based layer and which are <u>not</u> removed by step (b) of the present process. (Response pg 10, lines 18-22)

Applicant next argues:

Insofar as the lower phase (solvent based layer) is concerned, column 4, line 22 of Schmidt et al. indicates that it is filtered to remove "any remaining traces of oil or other contaminants". The only oil or other contaminants referred to the in '408 Patent specification are those that reside in the non-solvent layer. Thus, Schmidt et al. uses certain types of filter equipment to remove the last remaining traces of contaminants that spilled over from the separation process of step (b) so that the filtrate containing gelatin and glycerin is not contaminated with these non-solvent based contaminants. This is the only reasonable interpretation that can be applied to the clear teaching of the '408 specification. Thus, the description on page 3, paragraph 9 of the Office Action concerning what is fairly taught by the '408 Patent and particularly the reference to the removal of "any traces of oil or other contaminants" is a misreading of what is fairly taught in the '408 Patent. (Response pg 11, beginning at line 17)

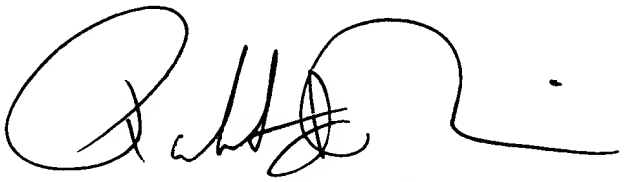
These arguments are not found persuasive since they are based on new matter which is unsupported by the originally filed specification. As set forth in the art rejections above, all of the particulate/oily contaminants will be inherently removed from the aqueous phase by the hot filtering.

Conclusion

18. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

19. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Examiner Robert Popovics whose telephone number is (703) 308-0684, and who can normally be reached at this number from 9:30 A.M. through 6:00 P.M. (EST) M-F.



Robert James Popovics
Primary Examiner
Art Unit 1723

rjp
May 18, 2002